



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0601; FRL-10400-01-OCSP]

2,6-Pyridinedicarboxylic Acid; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of 2,6-pyridinedicarboxylic acid, also known as DPA (CAS Reg. No. 499-83-2), when used as an inert ingredient in antimicrobial pesticide formulations for use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils and when used in pesticide formulations applied pre- and post-harvest to crops with an end-use concentration not to exceed 2 parts per million (ppm). EcoLab Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of such exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of DPA.

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0601, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions

provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0601 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0601, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets/about-epa-dockets>.

II. Petition for Exemption

In the *Federal Register* of February 11, 2020 (85 FR 7708) (FRL-10005-02), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide

petition (PP IN-11307) by EcoLab Inc., 1 Ecolab Place, St. Paul, MN 55102. The petition requested to amend an exemption from the requirement of a tolerance for residues of 2,6-pyridinedicarboxylic acid, also known as DPA, (CAS Reg. No. 499-83-2) by consolidating and expanding the current exemptions to 40 CFR 180.940(a) and increasing the limit to 2 parts per million (ppm) when used as a pesticide inert ingredient in pesticide formulations applied to hard, non-porous food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils. The petition also requested EPA establish an exemption from the requirement of a tolerance at 40 CFR 180.910, limited to 2 ppm when used in pesticide formulations applied to growing crops. That document referenced a summary of the petition prepared by EcoLab Inc, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to

the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for DPA including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with DPA follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also

considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by DPA as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The Agency assessed DPA via the Threshold of Toxicological Concern (TTC) approach as outlined by the European Food Safety Authority (EFSA) in their 2019 guidance document on the use of TTC in food safety assessment. This approach relies on the most recent evaluation of the literature on TTC as reviewed by EFSA and the World Health Organization (WHO) in 2016. Information regarding the database of studies and chemicals used to derive TTCs are reviewed therein. The TTC approach has been used by the Joint Expert Committee on Food Additives of the U.N.'s Food and Agriculture Organization and the World Health Organization, the former Scientific Committee on Food of the European Commission, the European Medicines Agency, and EFSA.

TTC are derived from a conservative and rigorous approach developed by Munro and Kroes to establish generic threshold values for human exposure at which a very low probability of adverse effects is likely. There are three Cramer Classes that are organized by structural classes using the Cramer (1978) decision scheme. By comparing a range of compounds by Cramer Class (classes I, II, and III) and no-observed-effect-level (NOEL), fifth percentile NOELs were established for each Cramer Class as "Human Exposure Thresholds" assuming a 60 kg human. These values were 3, 0.91 and 0.15 mg/kg/day for classes I, II and III, respectively.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>.

The human exposure threshold value for threshold (*i.e.*, non-cancer) risks for DPA is based upon Cramer structural class. DPA is categorized as Cramer class III based on the OECD QSAR toolbox analysis of the Cramer decision scheme; therefore, this assessment uses the NOEL of 0.15 mg/kg/day as the point of departure for all exposure scenarios assessed (chronic dietary, incidental oral, dermal and inhalation exposures).

C. Exposure Assessment

1. *Dietary exposure.* In evaluating dietary exposure to DPA, EPA considered exposure under the proposed tolerance exemptions at a concentration not to exceed 2 ppm of DPA in an end-use pesticide formulation, as well as any other sources of dietary exposure. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for DPA, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound.

Dietary exposure (food and drinking water) may occur from the existing and proposed uses of DPA (e.g., eating foods treated with pesticide formulations containing DPA, and drinking water exposures). An acute dietary assessment was not performed due to the lack of adverse effects attributed to a single dietary exposure.

2. *Residential exposure.* The term “residential exposure” is used in this document to refer

to non-occupational, non-dietary exposure (e.g., from hard surface disinfection on walls, floors, and tables).

DPA may be used as an inert ingredient in products that are registered for specific uses that may result in short-term and intermediate-term residential exposure, such as pesticides used in and around the home. The Agency conducted a conservative assessment of potential residential exposure by assessing DPA in pesticides in outdoor and indoor scenarios. The Agency's assessment of adult residential exposure combines high-end dermal and inhalation handler exposure from outdoor and indoor uses. The Agency's assessment of children's residential exposure includes total post-application exposures associated with total exposures to contact with both treated outdoor or indoor scenarios.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not made a common mechanism of toxicity finding as to DPA and any other substances, and DPA does not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that DPA has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA

determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. The FQPA SF has been reduced to 1X for DPA because clear NOELs and LOELs were established in the studies analyzed by Munro *et al* 1996 (which included developmental and reproductive toxicity studies), maternal and developmental-specific 5th percentile NOELs calculated by van Ravenzwaay *et al* 2011 indicate low potential for offspring susceptibility, there is no known precedent for developmental or reproductive toxicity potential for DPA using the QSAR Toolbox DART Scheme, and the conservative assumptions made in the exposure assessment are unlikely underestimate to risk.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute aggregate risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effects resulting from a single oral exposure were identified and no acute dietary endpoint were selected for DPA. Therefore, DPA is not expected to pose an acute risk.

2. *Short-term aggregate risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

DPA is currently used as an inert ingredient in pesticide products that are registered for

uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1400 for both adult males and females. EPA has concluded the combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 530 for children. Because EPA's level of concern for DPA is a MOE of 100 or below, these MOEs are not of concern.

3. *Intermediate-term aggregate risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, DPA exposure values for intermediate term risks are all lower than the short-term risk. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for DPA.

4. *Chronic aggregate risk.* A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions described in unit IV for chronic exposure, EPA has concluded that chronic exposure to DPA from food and water will utilize 18.1% of the cPAD for children 1 to 2 years old, the highest exposed subgroup. Therefore, chronic dietary risks are below the Agency's level of concern of 100% of the cPAD. The chronic aggregate risk is equal to the chronic dietary risk and is not of concern for DPA.

5. *Cancer aggregate risk.* No structural alerts for cancer were identified for DPA.

Therefore, there is low concern for genotoxicity/carcinogenicity in humans and the assessment under the TTC value for non-cancer risks is protective for all risks, including carcinogenicity.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to residues of DPA.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for DPA in or on any food commodities. EPA is establishing a limitation on the amount of DPA that may be used in pesticide formulations. This limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 *U.S.C. 136 et seq.* EPA will not register any pesticide formulation for food use that exceeds 2 ppm of 2,6-pyridinedicarboxylic acid in the final pesticide formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for 2,6-pyridinedicarboxylic acid, also known as DPA, (CAS Reg. No. 499-83-2) when used as an inert ingredient in antimicrobial pesticide formulations applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils at an end-use concentration not to exceed 2 ppm, and under 40 CFR 180.910 when used as an inert ingredient (stabilizer) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest at a concentration not to exceed 2 ppm.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCFA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these

types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 17, 2022.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR part 180 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.910, amend Table 1 to 180.910, by adding in alphabetical order, an entry for “2,6-pyridinedicarboxylic acid (CAS Reg. No. 449-83-2)” to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Table 1 to 180.910

Inert ingredients	Limits	Uses
* * * * *	*	*
2,6-pyridinedicarboxylic acid (CAS Reg. No. 449-83-2)	Not to exceed 2 ppm	Stabilizer
* * * * *	*	*

3. Amend §180.940, by:

- a. Adding in alphabetical order an entry for the pesticide chemical “2,6-Pyridinedicarboxylic acid” in table 1 to paragraph (a);
- b. Removing the entry for “2,6-Pyridinedicarboxylic acid” from the table in paragraph (b); and
- c. Removing the entry for “2,6-Pyridinedicarboxylic acid” from the table in paragraph (c).

The addition reads as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Table 1 to Paragraph (a)

Pesticide Chemical	CAS Reg. No.	Limits
* * *	* * *	* * *
2,6-Pyridinedicarboxylic acid	499-83-2	When ready for use, the end-use concentration is not to exceed 2 ppm
* * *	* * *	* * *

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[FR Doc. 2022-25582 Filed: 11/22/2022 8:45 am; Publication Date: 11/23/2022]